

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI

STATE OF MISSOURI, *et al.*,)
Plaintiffs,)
v.) Civil Action No. 4:21-cv-1329
JOSEPH R. BIDEN, JR., *et al.*,)
Defendants.)

**DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFFS'
MOTION TO LIFT THE STAY OF DISTRICT COURT PROCEEDINGS**

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INTRODUCTION

The Supreme Court has effectively resolved this case. In *Biden v. Missouri*, 142 S. Ct. 647 (2022), the Court held that the vaccination rule at issue here is within the Secretary’s statutory authority, and it explicitly rejected Plaintiffs’ claims that the rule is arbitrary and capricious, procedurally invalid, and contrary to law. Plaintiffs’ constitutional challenges were briefed and argued to the Supreme Court, and that Court implicitly rejected those claims as well.

The appeal of the preliminary injunction remains pending in the Eighth Circuit, and Plaintiffs have already filed their answering brief in that appeal. The Court of Appeals will decide if any claims in this case remain viable following the Supreme Court’s decision. While that appeal is pending, this Court is divested of jurisdiction to consider the same claims that are before the Eighth Circuit.

In any event, the Supreme Court’s reasoning forecloses Plaintiffs’ ostensibly new and supplemented claims. Plaintiffs argue that new factual and legal developments render the vaccination rule arbitrary and capricious. But the Supreme Court was well aware of the Omicron variant when it issued its decision, and it applied settled principles of administrative law to uphold the rule on the record that was before the Secretary at the time the rule was issued. Plaintiffs’ remaining arguments simply repackage their initial claim that the Secretary did not account for potential staffing issues in health care facilities. The Supreme Court has expressly rejected this argument, upholding the reasonableness of the Secretary’s judgment on this issue. Plaintiffs’ attempt to restate their claim under 42 U.S.C. § 1395z is also squarely foreclosed by the Supreme Court’s decision.

Nor is there merit to Plaintiffs’ challenge to guidance that the Centers for Medicare & Medicaid Services (CMS) recently issued for state survey agencies. That guidance concerns Section 1864 Agreements, under which CMS pays these agencies to survey health care facilities for compliance with Medicare and Medicaid conditions of participation. The guidance simply reminds these agencies that their payments under a Section 1864 Agreement may be reduced to the extent that they do not perform their end of the bargain. A State’s participation in such an agreement is entirely voluntary, and States are in no way “commandeered” by such a reminder of basic contract principles.

Plaintiffs’ motion to lift this Court’s stay of proceedings should accordingly be denied.

BACKGROUND

I. Prior Proceedings of This Litigation.

After this Court issued a preliminary injunction against the enforcement of the vaccination rule, ECF No. 28, Defendants filed a notice of appeal, ECF No. 29. Both this Court and the Eighth Circuit denied motions for a stay of the injunction pending appeal. ECF No. 35, ECF No. 38. Defendants then filed applications in the Supreme Court for a stay of this Court’s preliminary injunction and of a preliminary injunction entered against the same rule by the Western District of Louisiana.

Defendants filed a consent motion to stay proceedings pending both the Eighth Circuit’s resolution of their appeal and the Supreme Court’s decision on the stay application. ECF No. 39. This Court granted the stay of proceedings, “agree[ing] with the parties” that those decisions would “likely . . . guide further proceedings in this case,” and that a stay would “preserve the resources of the parties and this Court, and, consistent with the parties’ positions,” would not bring “prejudice or hardship to the parties that would warrant denying a stay of the proceedings.” ECF No. 40 at 2.

On January 13, 2022, the Supreme Court granted the stay applications and, as explained below, effectively resolved the merits of this case in Defendants’ favor. *Biden v. Missouri*, 142 S. Ct. 647 (2022).¹

Defendants filed their opening brief on appeal on February 3, 2022. Opening Br. for Appellants, *Missouri v. Biden*, No. 21-3725 (8th Cir. Feb. 3, 2022). Plaintiffs filed their answering brief on March 1, 2022. Br. for Appellees, *Missouri v. Biden*, No. 21-3725 (8th Cir. Mar. 1, 2022).

In the meantime, the *Louisiana* plaintiffs moved for leave to file an amended and supplemental complaint. *Louisiana v. Becerra*, No. 3:21-CV-03970, ECF No. 51 (W.D. La. Feb. 4, 2022). The district court held that it lacked jurisdiction over that proposed pleading because “almost all of th[os]e issues . . . relate to issues on appeal.” *Louisiana*, ECF No. 59, at 4-5. The court issued an indicative ruling that it would grant

¹ Thereafter, plaintiffs in other cases voluntarily dismissed their challenges to the vaccination rule. Texas moved to dismiss its complaint “in light of the Supreme Court’s ruling in *Biden v. Missouri*.” Pls.’ Mot. for Dismissal, *Texas v. Becerra*, No. 21-cv-00229-Z, ECF No. 63 (N.D. Tex. Jan. 18, 2022). The court granted the motion, citing the Supreme Court’s decision as good cause to do. Order, *Texas v. Becerra*, No. 21-cv-00229-Z, ECF No. 66 (N.D. Tex. Jan. 19, 2022). Florida likewise dismissed its complaint, “[g]iven the United States Supreme Court’s decision in *Biden v. Missouri*.” Notice of Dismissal, *Florida v. U.S. Dep’t of Health & Human Servs.*, No. 3:21-cv-2722-MCR-HTC, ECF No. 26 (N.D. Fla. Feb. 4, 2022).

the motion if the Fifth Circuit remanded the matter, but only with respect to an anti-commandeering claim and a challenge to an agency memorandum not at issue here. *Id.* at 5. The Fifth Circuit denied the motion to remand, holding that the plaintiffs had not presented appropriate grounds for such a remand and that the district court thus lacked jurisdiction to proceed. *Louisiana v. Becerra*, No. 21-30734, 2022 WL 445159 (5th Cir. Feb. 14, 2022), *reh'g denied*, (5th Cir. Mar. 3, 2022).

Plaintiffs here are attempting something similar. They have filed what they characterize to be an amended complaint, for the purpose of adding allegations that the vaccination rule is invalid as a result of factual developments arising after the rule was issued; restating their original claims; and adding a claim under the non-delegation doctrine as well as what they call a “changes in core circumstances” claim. First Am. Compl. ¶¶ 343-49, ECF No. 42. Plaintiffs have also moved to lift the stay of district court proceedings, ECF No. 43, and have filed a motion to expedite review of their motion to lift that stay, ECF No. 45.

II. CMS’s Implementation of the Vaccine Rule.

CMS has exercised its enforcement discretion to adjust the implementation schedule for the rule. After the Fifth Circuit’s partial grant of a stay of the *Louisiana* preliminary injunction, *Louisiana v. Becerra*, 20 F.4th 260 (5th Cir. 2021), and the Northern District of Texas’s grant of a preliminary injunction covering Texas, *see Texas v. Becerra*, Order, No. 2:21-cv-00229-Z (N.D. Tex. Dec. 15, 2021), no injunction applied with respect to health care facilities in States that were not plaintiffs in one of the pending cases. For these facilities, CMS announced that it would implement the rule on a modified timeline, with the deadline for Phase 1 implementation set at January 27, 2022, and for Phase 2 implementation set at February 28, 2022. *See CMS, Current Emergencies: Litigation Update for CMS Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule, Update #2* (Dec. 28, 2021), <https://perma.cc/SG58-SANF>. CMS also issued guidance to state survey agencies on enforcement of the rule in those states in which the rule was effective. *See CMS, Guidance for the Interim Final Rule – Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination* (Dec. 28, 2021), <https://perma.cc/K79Z-SATG>. The agency set forth enforcement markers at 30, 60, and 90 days after the guidance issued, and explained that it would “follow current enforcement procedures based on the level of deficiency cited during a survey.” *Id.*

After the Supreme Court issued its stay, CMS issued additional guidance to implement the rule.

See CMS, Guidance for the Interim Final Rule – Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination (Jan. 14, 2022), available at <https://perma.cc/3DTA-59QP>; CMS, *External FAQ: CMS Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule* (updated Jan. 20, 2022) (“External FAQ”), available at <https://perma.cc/ETC6-CABH>. (The agency also published separate guidance for Texas, where a preliminary injunction was lifted at a later date.) CMS explained that, for the States previously covered by this Court’s or the *Louisiana* court’s preliminary injunction, it would exercise its enforcement discretion to modify the timeline for compliance to set a February 14, 2022 deadline for Phase 1, and a March 15, 2022 deadline for Phase 2. *See External FAQ.* The agency set forth the same enforcement markers as it had in the December 28 guidance memorandum, but set the 30, 60, and 90 day markers to the issuance of the January 14 Guidance.

III. CMS’s Guidance for State Surveyors.

CMS separately issued guidance to state survey agencies on another topic. CMS, *State Obligations to Survey the Entirety of Medicare & Medicaid Health & Safety Requirements under the 1864 Agreement* (Feb. 9, 2022) (Section 1864 Mem.), available at <https://perma.cc/3H2V-U4RV>. This guidance concerns § 1864 of the Social Security Act, under which CMS enters into agreements to pay state or local agencies to conduct surveys to ascertain whether providers meet Medicare’s and Medicaid’s conditions of participation. A State’s decision to enter into a § 1864 Agreement is wholly voluntary. *See* 42 U.S.C. § 1395aa(a) (authorizing agreements with “any State which is able and willing”). If a State enters into such an agreement, however, in order to be paid, it obliges itself to conduct surveys to “assess compliance with Federal health, safety and quality standards,” 42 C.F.R. § 488.26(c)(1), using “the survey methods, procedures, and forms that are prescribed by CMS,” *id.* § 488.26(d). CMS’s guidance notifies state survey agencies that “States that fail to perform survey and certification functions” under the agreement may “receive a revised Survey and Certification budgetary allocation,” which would be “commensurate with the impact of the State actions and the federal resources needed to provide appropriate oversight of providers and suppliers.” Section 1864 Mem. at 2.

STANDARD OF REVIEW

Defendants, with Plaintiffs’ consent, moved to stay proceedings in this Court while the appeal

is pending, ECF No. 39, and this Court granted the motion, ECF No. 40 at 2. In moving to lift the stay of proceedings, Plaintiffs seek reconsideration of this order. *See Destifanes v. Bricklayers Loc. #1 of Mo. Suppl. Pension Fund*, No. 4:20-CV-00750-NCC, 2021 WL 842552, at *3 (E.D. Mo. Mar. 5, 2021) (treating motion to lift stay of proceedings as motion for reconsideration). A district court may reconsider an interlocutory ruling, but “should be loathe to do so in the absence of extraordinary circumstances such as where the initial decision was clearly erroneous and would work a manifest injustice.” *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 817 (1988). A motion to reconsider is “not a vehicle to identify facts or legal arguments that could have been, but were not, raised at the time the relevant motion was pending,” *Julianello v. K-V-Pharm. Co.*, 791 F.3d 915, 923 (8th Cir. 2015), but instead may be used to “correct any clearly or manifestly erroneous findings of fact or conclusions of law.” *Jiang v. Porter*, No. 4:15-CV-1008, 2016 WL 193388, at *1 (E.D. Mo. Jan. 15, 2016).

Plaintiffs seek to proceed on a pleading that they have mislabeled as an “amended complaint.” First Am. Compl., ECF No. 42. That pleading raises allegations of “transaction[s], occurrence[s], or event[s] that happened after the date of the pleading to be supplemented,” and so is a supplemental complaint, not an amended complaint. Fed. R. Civ. P. 15(d). A plaintiff may not file a supplemental complaint as of right, but instead must seek leave to do so. *See id.* Leave to file a supplemental complaint may be denied where the proposed pleading would be futile, or granting leave would work unfair prejudice for the defendant. *See Pharm. Rsch. & Mfrs. of Am. v. Williams*, 525 F. Supp. 3d 946, 953 (D. Minn. 2021), *appeal filed*, No. 21-1731 (8th Cir. Apr. 1, 2021).

ARGUMENT

I. THE PENDING APPEAL DEPRIVES THIS COURT OF JURISDICTION TO PROCEED ON THE SUPPLEMENTAL COMPLAINT.

The Court’s preliminary injunction order is currently pending before the Eighth Circuit. As a result, this Court lacks jurisdiction to proceed on Plaintiffs’ supplemental complaint.

It is hornbook law that once an appeal is noticed, the district court is divested of jurisdiction over any matter related to the appeal. *See Liddell v. Bd. of Educ.*, 73 F.3d 819, 822 (8th Cir. 1996). A “federal district court and a federal court of appeals should not attempt to assert jurisdiction over a

case simultaneously.” *Griggs v. Provident Consumer Discount Co.*, 459 U.S. 56, 58 (1982). The jurisdictional divestiture rule “serves two important interests. First, it promotes judicial economy for it spares a trial court from considering and ruling on questions that possibly will be mooted by the decision of the court of appeals. Second, it promotes fairness to the parties who might otherwise have to fight a confusing ‘two front war’ for no good reason, . . . avoiding possible duplication and confusion by allocating control between forums.” *United States v. Ledbetter*, 882 F.2d 1345, 1347 (8th Cir. 1989).

Thus, “while an appeal is pending, the district court may not reexamine or supplement the order being appealed.” *Missouri v. Coeur D’Alene Tribe*, 164 F.3d 1102, 1106 (8th Cir. 1999); *see also Liddell*, 73 F.3d at 822 (“Once appealed, issues before an appellate court should not be undermined or altered.”). Nor may the district court take any action that would “alter the status of the case as it rests before the Court of Appeals.” *Knutson v. AG Processing, Inc.*, 302 F. Supp. 2d 1023, 1030 (N.D. Iowa 2004); *see also Wooten v. Roach*, 964 F.3d 395, 403 (5th Cir. 2020) (district court lacked jurisdiction to allow an amended complaint while interlocutory appeal was pending); *Green Leaf Nursery v. E.I. DuPont De Nemours & Co.*, 341 F.3d 1292, 1309 (11th Cir. 2003) (same); *Moon v. Pratte*, No. 4:13CV2570 JAR, 2014 WL 2765721, at *1 (E.D. Mo. June 18, 2014); Allan Ides, The Authority of a Federal District Court to Proceed After a Notice of Appeal has Been Filed, 143 F.R.D. 307, 308 (1992).

Plaintiffs’ proposed supplemental complaint would alter the status of the case before the court of appeals. Their new allegations are based on their view that “core circumstances have changed” due to the Omicron variant or the withdrawal of a separate rule issued by the Occupational Safety and Health Administration. *See* First Am. Compl. ¶¶ 184, 186, 242, ECF No. 42. But the Supreme Court was well aware of the emergence of the Omicron variant when it heard argument and issued its decision. And the Court obviously was also aware that it was issuing an opinion staying the OSHA rule on the same day that it rejected Plaintiffs’ challenges to the vaccine rule. Under the jurisdictional divestiture doctrine, this Court is jurisdictionally barred from addressing Plaintiffs’ attempt to reframe their challenge to the rule, and thereby reframing the appeal currently pending before the Eighth Circuit. *See Coeur D’Alene Tribe*, 164 F.3d at 1105-06; *Liddell*, 73 F.3d at 822.

Plaintiffs, moreover, admit that they intend to file a second motion for a preliminary injunction

to prohibit the Secretary from implementing the same vaccination rule. *See* Pls.’ Mem. in Supp. of Mot. to Lift the Stay of the Dist. Ct. Proceedings (Pls.’ Mem.) at 7, ECF No. 44. Plaintiffs may not circumvent the Supreme Court’s stay order in this manner. This Court would invalidly “disrupt[] the status quo by imposing an injunction where the Supreme Court had stayed the preexisting injunctions.” *New York v. U.S. Dep’t of Homeland Sec.*, 974 F.3d 210, 215 (2d Cir. 2020).²

Even if this Court were inclined to lift the stay or to entertain a motion for leave to file a supplemental complaint, this Court may do no more than enter an indicative ruling stating that it would so proceed if the Court of Appeals were to permit it to do so. *See* Fed. R. Civ. P. 62.1(a)(3); *see also Jackson v. Allstate Ins. Co.*, 785 F.3d 1193, 1206 (8th Cir. 2015). Plaintiffs could then provide notice to the court of appeals of this Court’s indicative ruling, and could seek a remand from that court for the purpose of allowing this Court to issue its order. *See* Fed. R. Civ. P. 62.1(b); Fed. R. App. P. 12.1(a), (b). Upon a remand, this Court could then rule on Plaintiffs’ motion. *See* Fed. R. Civ. P. 62.1(c). Until such an order is entered, however, this Court lacks jurisdiction to grant Plaintiffs leave to proceed.

II. THE PROPOSED SUPPLEMENTAL COMPLAINT’S CHALLENGE TO THE INTERIM FINAL RULE IS FUTILE.

Even if this Court had jurisdiction to consider Plaintiffs’ motion to lift the stay of proceedings, that motion should be denied because Plaintiffs’ claims would be futile.

A. The Supreme Court’s Decision Effectively Forecloses the Claims in Plaintiffs’ Supplemental Complaint.

In *Biden v. Missouri*, 142 S. Ct. 647 (2022), the Supreme Court stayed this Court’s preliminary injunction. In so ruling, the Court effectively resolved each of the issues presented in Plaintiffs’ original complaint and in Plaintiffs’ proposed supplemental complaint, in Defendants’ favor.

The Supreme Court held, *first*, that “the Secretary’s rule falls within the authorities that Congress has conferred upon him.” *Id.* at 652. The Secretary has the “general statutory authority to

² The Eighth Circuit has recognized a narrow exception to the jurisdictional divestiture rule arising out of a case involving continuing district court supervision of a school desegregation decree. *See Bd. of Educ. of St. Louis v. Missouri*, 936 F.2d 993, 996 (8th Cir. 1991). This limited exception does not apply here, as this Court is not supervising a decree governing a continuing course of conduct between the parties; the Supreme Court, of course, has stayed this Court’s prior preliminary injunction order.

promulgate regulations ‘as may be necessary to the efficient administration of the functions with which [he] is charged.’” *Id.* at 650 (quoting 42 U.S.C. § 1302(a)). “One such function—perhaps the most basic, given the Department’s core mission—is to ensure that the healthcare providers who care for Medicare and Medicaid patients protect their patients’ health and safety.” *Id.* “To that end, Congress authorized the Secretary to promulgate, as a condition of a facility’s participation in the programs, such ‘requirements as [he] finds necessary in the interest of the health and safety of individuals who are furnished services in the institution.’” *Id.* (quoting 42 U.S.C. § 1395x(e)(9)). The Court noted that, “[r]elying on these authorities, the Secretary has established long lists of detailed conditions with which facilities must comply to be eligible to receive Medicare and Medicaid funds.” *Id.* “Such conditions have long included a requirement that certain providers maintain and enforce an ‘infection prevention and control program designed . . . to help prevent the development and transmission of communicable diseases and infections.’” *Id.* at 650-51 (quoting 42 C.F.R. § 483.80).

The Court cited the Secretary’s findings that the rule “will substantially reduce the likelihood that healthcare workers will contract the virus and transmit it to their patients,” and that “a vaccine mandate is necessary to promote and protect patient health and safety in the face of the ongoing pandemic.” *Id.* at 652 (citing 86 Fed. Reg. at 61,557-61,558, 61,613). The Court concluded that

[t]he rule thus fits neatly within the language of the statute. After all, ensuring that providers take steps to avoid transmitting a dangerous virus to their patients is consistent with the fundamental principle of the medical profession: first, do no harm. It would be the “very opposite of efficient and effective administration for a facility that is supposed to make people well to make them sick with COVID-19.”

Id. (quoting *Florida v. Dep’t of Health & Human Servs.*, 19 F.4th 1271, 1288 (11th Cir. 2021)). The vaccination rule thus “is a straightforward and predictable example of the ‘health and safety’ regulations that Congress has authorized the Secretary to impose.” *Id.* at 653.

Second, the Court held that the Secretary had good cause to issue the vaccination rule as an interim final rule, because “the Secretary’s finding that accelerated promulgation of the rule in advance of the winter flu season would significantly reduce COVID-19 infections, hospitalizations, and deaths constitutes the ‘something specific,’ required to forgo notice and comment.” *Id.* at 654 (citations

omitted). Further, the Court rejected the argument that “the two months the agency took to prepare a 73-page rule constitutes ‘delay’ inconsistent with the Secretary’s finding of good cause.” *Id.*

Third, the Supreme Court “agree[d] with the Secretary that he was not required to ‘consult with appropriate State agencies,’ 42 U.S.C. § 1395z, in advance of issuing the rule. Consistent with the existence of the good cause exception, which was properly invoked here, consultation during the deferred notice-and-comment period is permissible.” *Id.*

Fourth, the Court “similarly concur[red] with the Secretary that he need not prepare a regulatory impact analysis discussing a rule’s effect on small rural hospitals when he acts through an interim final rule; that requirement applies only where the Secretary proceeds on the basis of a ‘notice of proposed rulemaking,’ followed by a ‘final version of [the] rule.’” *Id.* (quoting 42 U.S.C. § 1302(b)(1), (b)(2)).

Fifth, the Court held that the rule is not arbitrary and capricious.

Given the rulemaking record, it cannot be maintained that the Secretary failed to ‘examine the relevant data and articulate a satisfactory explanation for’ his decisions to (1) impose the vaccine mandate instead of a testing mandate; (2) require vaccination of employees with “natural immunity” from prior COVID-19 illness; and (3) depart from the agency’s prior approach of merely encouraging vaccination.

Id. at 653-54. The Court also disagreed “that the Secretary ‘entirely failed to consider’ that the rule might cause staffing shortages, including in rural areas.” *Id.* at 654. And it rejected the lower courts’ criticism of other parts of “the Secretary’s analysis, particularly concerning the nature of the data relied upon,” *id.*, noting that the courts’ role “is to ‘simply ensur[e] that the agency has acted within a zone of reasonableness.’” *Id.* (quoting *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021)).

Finally, the Court held that it “disagree[d] with respondents’ remaining contentions in support of the injunctions entered below.” *Id.* at 653. These remaining contentions included several constitutional arguments, as explained more fully below.

The decision effectively forecloses each claim in Plaintiffs’ proposed supplemental complaint. Plaintiffs seek to reassert claims that the rule was arbitrary and capricious either for reasons existing at the time of the rule or due to after-arising facts (Counts I, XI); that the Secretary lacked statutory authority for the rule (Count II); that the Secretary lacked good cause to issue the rule without notice

and comment (Counts III, IV); that 42 U.S.C. §§ 1302 and 1395z required the Secretary to prepare a regulatory impact analysis and to consult with state agencies before issuing the rule (Counts V, VI); and that the rule is unconstitutional under the Spending Clause, the anti-commandeering doctrine, the Tenth Amendment, or the nondelegation doctrine (Counts VII-X). The Supreme Court has flatly held to the contrary on Plaintiffs' statutory and procedural claims. *Biden v. Missouri*, 142 S. Ct. at 652-54. As to Plaintiffs' constitutional claims, the Supreme Court's rejection of each of "the respondents' remaining contentions," *id.* at 653, forecloses these claims as well. Likewise, the Supreme Court's stay of the preliminary injunction forecloses any attempt to seek a new injunction of the same rule.

Plaintiffs may not avoid the binding effect of the Supreme Court's decision, in this very case, by citing to Justice Kavanaugh's concurrence in *Merrill v. Milligan*, 142 S. Ct. 879 (2022). *See* Pls.' Mem. at 3, ECF No. 44. In that case, the majority issued a stay without an opinion explaining its reasoning, and Justice Kavanaugh concurred to note that he did not view that stay order as a decision on the merits. The Supreme Court may decide a stay application without finally deciding the merits of legal questions. But that is not what happened in *Biden v. Missouri*. In this case, the Court squarely decided the merits of Plaintiffs' claims in an opinion issued after holding oral argument on the stay applications, and it did not qualify those holdings in any way. *See Biden v. Missouri*, 142 S. Ct. at 652-54. That decision is binding on this Court, just as it is on any other lower court that would hear a similar challenge.

B. Plaintiffs' Constitutional Claims Are Futile.

Plaintiffs fare no better with their attempt to reassert their constitutional claims. Those claims were briefed to the Supreme Court. Although this Court did not rely on Plaintiffs' constitutional claims in issuing its preliminary injunction, the district court in the Louisiana case did, and the *Louisiana* plaintiffs argued to the Supreme Court that the rule exceeded Congress's Spending Clause power, was impermissibly coercive, and was unconstitutional under the nondelegation doctrine. *See* Response to Application for a Stay Pending Appeal at 1, 23-27, *Becerra v. Louisiana*, Nos. 21A240, 21A241 (U.S. Dec. 30, 2021). The *Louisiana* plaintiffs argued that, at a minimum, the Supreme Court should interpret the statute to avoid the asserted constitutional problems. *See id.* at 27. The Supreme Court, indicating that it "disagree[d] with respondents' remaining contentions in support of the injunctions entered

below,” *id.* at 653, ruled in the Secretary’s favor and interpreted the statute to authorize the rule. Accordingly, the Court effectively resolved Plaintiffs’ constitutional claims, and this renders futile any attempt to revive those same arguments. *See Thompson v. Comm’r*, 821 F.3d 1008, 1011 (8th Cir. 2016) (law of the case doctrine establishes that “every question decided by the appellate court, whether expressly or by necessary implication, is finally settled and determined”).

It is unsurprising that the Supreme Court disposed of the constitutional claims so easily. “Congress has authority under the Spending Clause to appropriate federal funds to promote the general welfare” and “to see to it that taxpayer dollars appropriated under that power are in fact spent for the general welfare.” *Sabri v. United States*, 541 U.S. 600, 605 (2004). Congress’s power to impose conditions on federal funds applies regardless of whether Congress legislates “in an area historically of state concern.” *Id.* at 608 n.*.

The Supreme Court’s decision thus effectively forecloses Plaintiffs’ assertion that they lacked adequate notice that the Secretary might impose a funding condition like the vaccination rule. The Court explained that the rule “is not a surprising one.” *Biden v. Missouri*, 142 S. Ct. at 653. The Secretary “routinely imposes conditions of participation that relate to the qualifications and duties of healthcare workers themselves,” and “[v]accination requirements are a common feature of the provision of healthcare in America,” *id.* Plaintiffs made no attempt to square their Spending Clause argument with the Secretary’s “longstanding litany of health-related participation conditions,” the validity of which Plaintiffs did not contest. *Id.* The Supreme Court’s conclusion that the rule “is a straightforward and predictable example of the ‘health and safety’ regulations that Congress has authorized the Secretary to impose,” *id.*, likewise effectively forecloses any contention that Congress’s grant of these authorities to the Secretary poses any issue under the non-delegation doctrine. *See Bhatti v. FHFA*, 15 F.4th 848, 854 (8th Cir. 2021).

Nor may Plaintiffs avoid the Supreme Court’s decision by recasting their “coercion” theory as an “anti-commandeering” claim. There is no meaningful difference between those allegations. Because the Court upheld the vaccine rule as a valid condition on federal funds, a lower court could not deem the rule to be an impermissible “commandeering” of state-run facilities. Valid conditions on the

receipt of federal funds do not constitute commandeering. *New York v. United States*, 505 U.S. 144, 167, 173 (1992) (contrasting funding conditions with commandeering). Moreover, the vaccination rule imposes the same conditions on health care facilities that participate in the Medicare or Medicaid programs, no matter whether those facilities are privately-run or State-run. The Secretary did not run afoul of the anti-commandeering principle by imposing these conditions on equal terms. *See Murphy v. NCAA*, 138 S. Ct. 1461, 1478 (2018) (“The anticommandeering doctrine does not apply when Congress evenhandedly regulates an activity in which both States and private actors engage.”).

C. The Emergence of the Omicron Variant Does Not Provide Any Basis to Revive Plaintiffs’ Claims.

Plaintiffs cannot avoid the binding effect of *Biden v. Missouri* by asserting, mere weeks after the Supreme Court issued its decision, that the Court got the facts wrong. Plaintiffs did not file a petition for rehearing in the Supreme Court. Despite failing to pursue this option, Plaintiffs now ask this Court to revisit the Supreme Court’s holdings by asserting that the emergence—in December 2021 and January 2022—of the Omicron variant of the SARS-CoV-2 virus demonstrates that the Secretary acted arbitrarily and capriciously—in early November 2021—when he issued his rule, or that he lacked good cause to do so at that time. This request misconstrues the nature of APA review of rulemaking.

“It is well-established that judicial review under the APA is limited to the administrative record that was before the agency *when it made its decision.*” *Voyageurs Nat'l Park Ass'n v. Norton*, 381 F.3d 759, 766 (8th Cir. 2004) (emphasis added); *see Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 743-44 (1985). This is because “the focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court.” *Camp v. Pitts*, 411 U.S. 138, 142 (1973). The Supreme Court reviewed the administrative record already in existence, and held that, “[g]iven the rulemaking record, it cannot be maintained that the Secretary [had] failed to examine the relevant data,” or that he had committed any other procedural or substantive violation. *Biden v. Missouri*, 142 S. Ct. at 653-54. That holding remains binding on this Court.

Auer v. Robbins, 519 U.S. 452 (1997), makes clear that Plaintiffs may not challenge the validity of the rule based on later-arising facts. The plaintiffs in *Auer* asserted that new developments had

rendered a regulation arbitrary and capricious. The Supreme Court rejected this claim, holding that “there is no basis for the court to set aside the agency’s action prior to any application for relief addressed to the agency itself” through a petition for a new rulemaking under 5 U.S.C. § 553(e). *Id.* at 459; *see also Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016); *Alon Refin. Krotz Springs, Inc. v. EPA*, 936 F.3d 628, 643 (D.C. Cir. 2019).³

The Supreme Court’s holding would bind this Court even if there were reason to believe that the factual circumstances had changed. But there is no reason to doubt the correctness of the Supreme Court’s decision or the reasonableness of the rulemaking. *First*, the Secretary explicitly considered the potential emergence of new variants and determined that this possibility supported the rule itself and the finding of good cause. *See, e.g.*, 86 Fed. Reg. at 61,583-84. For this reason, and for the many other factors the Secretary explicitly considered, Plaintiffs’ assertion that the Delta variant provided the sole rationale for the rule, *see First Am. Compl. ¶ 349*, is not supported by the record.

Second, contrary to Plaintiffs’ characterizations of the Omicron variant as “mild,” January and February 2022 have been among the pandemic’s deadliest months; at least 107,000 Americans have died of COVID-19 this year. Centers for Disease Control & Prevention (“CDC”), *COVID-19 Mortality Overview*, <https://perma.cc/639P-RJ8F> (last visited Mar. 8, 2022). These deaths occurred chiefly among unvaccinated people; the most recent data available shows that the unvaccinated are 14 times more likely to die from COVID-19 than are the vaccinated. CDC, *Rates of COVID-19 Cases and Deaths by Vaccination Status*, <https://perma.cc/A85B-6ERU> (last visited Mar. 8, 2022). The most recent data available also shows that unvaccinated adults are 7 times more likely to be hospitalized from COVID-19 than vaccinated adults are. CDC, *Rates of Laboratory-Confirmed COVID-19 Hospitalizations by Vaccination Status*, <https://perma.cc/HV7M-7V48> (last visited Mar. 8, 2022).

³ Plaintiffs may not avoid the effect of *Auer* by recasting their arbitrary-and-capricious claim as a cause of action for “Changes in Core Circumstances.” No such cause of action exists. *Auer* makes clear that a plaintiff may not challenge the validity of a rule by pointing to facts arising after the rule was issued, and the cases that Plaintiffs cite to support their so-called “changes in core circumstances” claim all pre-date *Auer* by several decades. *See First Am. Compl. ¶ 344* (citing *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 172 (1962), and *Am. Optometric Ass’n v. FTC*, 626 F.2d 896, 907 (D.C. Cir. 1980)).

Fully vaccinated people with a booster shot are better protected than those without a booster shot, but even the latter group remains much better protected against the virus than are unvaccinated people. The COVID-19 hospitalization rate for the unvaccinated, even after Omicron's emergence, is 5.3 times higher than that for fully vaccinated people without a booster shot, and 23 times higher than for fully vaccinated people with a booster shot.⁴ And unvaccinated people—again, after Omicron's emergence—are 3.1 times more likely to contract COVID-19 than are fully vaccinated persons.⁵

The benefits of vaccination are particularly relevant now, as a new version of the Omicron variant, the BA.2 subvariant, begins to take hold in the United States. CDC, *Covid Data Tracker: Variant Proportions*, <https://covid.cdc.gov/covid-data-tracker/#variant-proportions> (last visited Mar. 9, 2022). This subvariant spreads even more easily than the original Omicron variant does, and may lead to a renewed surge in COVID-19 cases in the coming weeks. *Id.* Fortunately, the most recent evidence indicates that the vaccinated are significantly less likely to transmit Omicron, including this subvariant, than are the unvaccinated.⁶

There is no reason, then, to doubt the accuracy of the Secretary's findings that the rule "is 'necessary to promote and protect patient health and safety' in the face of the ongoing pandemic," *Biden v. Missouri*, 142 S. Ct. at 652 (citing 86 Fed. Reg. at 61,557-61,558, 61,613), or the Supreme Court's holding that the Secretary had "acted within a zone of reasonableness" in so finding, *id.* at 654 (citation omitted). That holding is binding on this Court, and this Court should reject Plaintiffs' invitation to

⁴ Phoebe Danza et al., *SARS-CoV-2 Infection and Hospitalization Among Adults Aged ≥18 Years, by Vaccination Status, Before and During SARS-CoV-2 B.1.1.529 (Omicron) Variant Predominance—Los Angeles County, California, November 7, 2021–January 8, 2022*, 71 Morbidity & Mortality Weekly Report 177 (Feb. 4, 2022), <https://perma.cc/JWV9-ACFR>.

⁵ Amelia G. Johnson, et al., *COVID-19 Incidence and Death Rates Among Unvaccinated and Fully Vaccinated Adults with and Without Booster Doses During Periods of Delta and Omicron Variant Emergence — 25 U.S. Jurisdictions, April 4–December 25, 2021*, 71 Morbidity & Mortality Weekly Report 132 (Jan. 28, 2022), <https://perma.cc/Y9XF-DSE3..>

⁶ See Julia M. Baker et al., *SARS-CoV-2 B.1.1.529 (Omicron) Variant Transmission Within Households — Four U.S. Jurisdictions, November 2021–February 2022*, 71 Morbidity & Mortality Weekly Report 341 (Mar. 4, 2022), <https://perma.cc/74S8-AW47>; see also Samira Sami et al., *Investigation of SARS-CoV-2 Transmission Associated With a Large Indoor Convention — New York City, November–December 2021*, 71 Morbidity & Mortality Weekly Report 243 (Feb. 18, 2022), <https://perma.cc/58T3-QGKN>; Frederik Plesner Lyngse et al., *Transmission of SARS-CoV-2 Omicron VOC subvariants BA.1 and BA.2: Evidence from Danish Households*, medRxiv (Jan. 30, 2022) (pre-print), <https://perma.cc/FFX3-C3MY>.

defy the precedential decision that the Supreme Court has issued in this very case.

D. Other Legal and Regulatory Developments Do Not Upset the Court’s Conclusions.

Plaintiffs raise a host of additional arguments to circumvent the Supreme Court’s holding. These arguments are meritless as well.

Health Care Staffing Shortages. The Secretary found that, on balance, his rule would alleviate staffing shortages, by reducing staff absenteeism due to illness and by encouraging personnel who were concerned for their own safety to return to work, 86 Fed. Reg. at 61,569-70, 61,608, and the Supreme Court has upheld that finding, *Biden v. Missouri*, 142 S. Ct. at 654. Plaintiffs may not relitigate that issue by pointing to events that post-date the rule. *See Auer*, 519 U.S. at 459. In any event, Plaintiffs’ careful phrasing in their motion and supplemental complaint reveals no actual allegation that the rule has caused any new burdens. *See* Pls.’ Mem. at 5-6 (alleging that health care facilities have submitted closure plans, but not alleging that these plans were caused by the rule). It is unsurprising that they do not directly so allege. That is because, since the rule’s implementation, it has become clear that “[t]he doomsday predictions” from those challenging the IFR simply “have not been borne out.” *Rural Hospitals Stave Off Mass Exodus of Workers to Vaccine Mandate*, Politico (Feb. 22, 2022), <https://perma.cc/K88N-DPNU>. And nothing in Plaintiffs’ allegations calls into question the reasonableness of the Secretary’s conclusions that, on balance, his rule will help to alleviate staffing shortages by reducing staff absenteeism due to illness and by encouraging personnel who were concerned for their own safety to return to work. *See* 86 Fed. Reg. at 61,569-70, 61,608. Plaintiffs cannot now use these disproven predictions as a basis to revive their suit.

The OSHA ETS. Nor can Plaintiffs avoid the binding effect of *Biden v. Missouri* by asserting that “the legal and regulatory landscape has drastically changed” in any other way since the rule was issued. First Am. Compl. ¶ 346. Notwithstanding Plaintiffs’ allegation that the rule “was initially designed to work in tandem with vaccine mandates on other types of employers,” First Am. Compl. ¶¶ 248, 346, the rule makes no mention of any other federal vaccination requirement—let alone

indicates that it depended on an expectation of their enforcement.⁷

Plaintiffs contend that the non-enforcement of other federal vaccination rules means health care staff will be “more freely able to leave [covered] employers . . . and seek employment elsewhere” which “will further worsen the staffing shortages in the healthcare sector.” First Am. Compl. ¶ 248. They argue that this renders the vaccination rule “irrational[.]” *Id.* At bottom, Plaintiffs are simply putting a new spin on the same argument they have advanced from the start of this litigation: that the Secretary did not adequately account for potential staffing issues that his vaccination rule might cause. *See* Pl. States’ Mem. in Supp. of Mot. for Prelim. Inj., at 16-19, ECF No. 9.

The Supreme Court has already expressly rejected this argument. *Biden v. Missouri*, 142 S. Ct. at 654. In fact, none of the federal vaccination rules to which Plaintiffs allude were yet in place when various private health care systems successfully imposed their own vaccine requirements. *See* 86 Fed. Reg. at 61,566 (citing, as examples, health care systems in Delaware, Texas, and North Carolina that “all preceded this rule with their own vaccination requirements, achieving rates of at least 97 percent vaccination among their staff”). The Supreme Court upheld the reasonableness of the Secretary’s reliance on the experience of these systems, *see Biden v. Missouri*, 142 S. Ct. at 654, in accordance with a long line of authorities that defer to an agency’s weighing of competing considerations in making predictive judgments, *see id.* (citing *Prometheus Radio Project*, 141 S. Ct. at 1158); *see also Citizens Telecomm. Co. of Minn., LLC v. FCC*, 901 F.3d 991, 1010 (8th Cir. 2018).

Further, the Supreme Court was well aware when it stayed this Court’s preliminary injunction and allowed enforcement of the rule that, in an opinion issued that same day, it was simultaneously staying enforcement of the OSHA ETS. And that Court has not passed on the enforceability of the other federal vaccination rules that Plaintiffs reference. Accordingly, whatever “legal developments”

⁷ Plaintiffs may have misunderstood the rule’s reference to an “OSHA ETS” to be to the Vaccination or Testing ETS adopted by the Occupational Safety and Health Administration, *COVID-19 Vaccination and Testing: Emergency Temporary Standard*, 86 Fed. Reg. 61402 (Nov. 5, 2021). In fact, the reference is to *COVID-19 Healthcare Emergency Temporary Standard, Occupational Exposure to COVID-19; Emergency Temporary Standard*, 86 Fed. Reg. 32376 (June 21, 2021), which concerned protecting health care and health care support service workers from occupational exposure to COVID-19. *See* 86 Fed. Reg. at 61,561. That rule was not at issue in the Supreme Court.

may “have rendered unenforceable the other federal vaccine mandates,” Pls.’ Mem. at 7, they do not undercut the Supreme Court’s clear conclusion that *this vaccination rule* may be enforced.

Enforcement Discretion. Nor should Plaintiffs be heard to allege that CMS’s exercise of its enforcement discretion to delay the rule’s enforcement somehow renders the rule arbitrary. *See First Am. Compl.* ¶ 250. The rule always contemplated that enforcement guidance would follow its issuance. 86 Fed. Reg. at 61,574. CMS was preliminarily enjoined from implementing the rule with respect to facilities in the Plaintiff States until January 13, 2022, and could hardly have enforced the rule during that time. Once the injunctions were lifted, CMS reasonably determined that it was appropriate to give providers time to implement policies and employees time to obtain vaccinations—a determination Plaintiffs do not challenge here, and could not be harmed by. CMS acted well within its enforcement discretion, which courts traditionally “deem[] to be unreviewable.” *GoJet Airlines, LLC v. FAA*, 743 F.3d 1168, 1173 (8th Cir. 2014).

State Survey Agency Guidance. Plaintiffs’ challenge to CMS’s recent guidance for state survey agencies does not implicate the validity of the vaccination rule itself. That challenge is also futile. CMS has not “commandeered” state employees in any way. A State’s decision to enter into a Section 1864 Agreement is entirely voluntary. *See 42 U.S.C. § 1395cc(a)*. CMS’s guidance simply reminds States that they have no entitlement to payment under the Section 1864 Agreement for work that they choose not to perform. The only funding that a State would lose if it declined to fulfill its end of the bargain would be payments under the Section 1864 Agreement itself. *Contra Nat’l Fed’n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 579-80 (2012); *see Gruver v. La. Bd. of Supervisors for La. State Univ. Agric. & Mech. Coll.*, 959 F.3d 178, 184 (5th Cir.), *cert. denied*, 141 S. Ct. 901 (2020).

Section 1395z Consultation. Plaintiffs also seek to revive a claim that 42 U.S.C. § 1395z required the Secretary to consult with state agencies prior to issuing the rule. The Supreme Court squarely rejected this claim. *Biden v. Missouri*, 142 S. Ct. at 654. The Court “agree[d] with the Secretary that he was not required to consult . . . in advance of issuing the interim rule.” 142 S. Ct. at 654. Plaintiffs now contend that the Secretary was obliged to engage in consultations on or before January 4, 2022. *First Am. Compl.* ¶ 299. This argument does not cast doubt on the validity of the rule, which the

Supreme Court has upheld. If Plaintiffs seeks to challenge a later final agency action on this ground, they must await the issuance of that action.

The argument is also meritless. The Supreme Court stated that “consultation during the deferred notice-and-comment period [was] permissible,” *id.*, but not that the law imposed a cutoff date on those consultations. In any event, CMS *has* engaged in consultations with state and local agencies. In addition to receiving written comments from States during the comment period, CMS also directly engaged in telephone consultations with the appropriate State agencies. On February 16, 2022, CMS held a call to solicit feedback on the rule from the members of the Association of Health Facility Survey Agencies (“AHFSA”), an organization that includes the state survey agencies and the Accrediting Organizations. Decl. of Karen Tritz ¶ 8. As CMS stated in opening the call, its purpose was to provide ““a dedicated opportunity to hear from State Agencies and Accrediting Organizations” about the rule, ““including experiences in enforcing the rule and input on policy concerning the conditions of participation related to staff vaccinations.”” *Id.* ¶ 10. During the call, representatives of a number of state survey agencies and of several accrediting organizations provided comments to CMS. *Id.* ¶ 11. Accordingly, Defendants have met their Section 1395z consultation obligations.

III. DEFENDANTS WOULD BE PREJUDICED IF THE STAY OF PROCEEDINGS WERE TO BE LIFTED.

Finally, Defendants face unfair prejudice if the stay of proceedings were to be lifted now. Plaintiffs seek to proceed in this Court on matters that are duplicative of the pending appeal. This tactic would waste the resources of the parties and the Court, and threaten conflicting rulings. *See Willis Elec. Co. v. Polygroup Ltd.*, No. 15-CV-3443-WMW-KMM, 2018 WL 4815563, at *1 (D. Minn. Oct. 4, 2018). It would be inappropriate to proceed in this Court now while Plaintiffs’ challenge to the same rule is pending before the Eighth Circuit. *See Intell. Ventures I LLC v. PNC Fin. Servs. Grp., Inc.*, No. 14CV0832, 2015 WL 12778404, at *1 (W.D. Pa. Oct. 27, 2015). *Accord Minnesota ex rel. Ellison v. Am. Petroleum Inst.*, No. CV 20-1636 (JRT/HB), 2021 WL 3711072, at *4 (D. Minn. Aug. 20, 2021).

CONCLUSION

For the foregoing reasons, Plaintiffs’ motion to lift the stay of proceedings should be denied.

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Respectfully submitted,

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